

1 “(B) By substitution in or on the phenethyl
2 group with alkyl, alkenyl, alkoxy, hydroxyl, halo,
3 haloalkyl, amino, or nitro groups.

4 “(C) By substitution in or on the piperidine
5 ring with alkyl, alkenyl, alkoxy, ester, ether,
6 hydroxyl, halo, haloalkyl, amino, or nitro groups.

7 “(D) By replacement of the aniline ring with
8 any aromatic monocycle whether or not further sub-
9 stituted in or on the aromatic monocycle.

10 “(E) By replacement of the N-propionyl group
11 with another acyl group.

12 “(3) A substance that meets the criteria specified in
13 paragraph (2) to be considered a fentanyl-related sub-
14 stance shall not be so considered as meeting such criteria
15 if such substance—

16 “(A) is controlled by action of the Attorney
17 General pursuant to section 201;

18 “(B) is expressly listed in this schedule or an-
19 other schedule by a statutory provision other than
20 this subsection; or

21 “(C) is removed from this schedule, or resched-
22 uled to another schedule, pursuant to section 201(k).

23 “(4) The Attorney General shall publish in the Fed-
24 eral Register a list of individual substances that meet the
25 definition of fentanyl-related substances in paragraph (2)

1 within 60 days of determining such substances meet such
2 definition. The absence of a substance on any such list
3 does not negate the control status of such substance if
4 the substance meets the criteria specified in paragraph (2)
5 to be considered a fentanyl-related substance.

6 “(5) Notwithstanding any other provision of this title
7 or title III, fentanyl-related substances shall not be subject
8 to quantity-based mandatory minimum penalties pursuant
9 to subparagraph (A)(vi) or (B)(vi) of section 401(b)(1) of
10 this title or paragraph (1)(F) or (2)(F) of section 1010(b)
11 of title III.”

12 **SEC. 3. PENALTY PROVISIONS WITH RESPECT TO**
13 **FENTANYL-RELATED SUBSTANCES—DOMES-**
14 **TIC OFFENSES.**

15 Section 401(b)(1) of the Controlled Substances Act
16 (21 U.S.C. 841(b)(1)) is amended—

17 (1) in subparagraph (A), by striking clause (vi)
18 and inserting the following:

19 “(vi)(I) 400 grams or more of a mixture or sub-
20 stance containing a detectable amount of fentanyl;
21 or

22 “(II) 100 grams or more of a mixture or sub-
23 stance containing a detectable amount of any ana-
24 logue of fentanyl that is controlled in schedule I or
25 II or that is treated as a schedule I controlled sub-

1 stance pursuant to section 203(a), except for a
2 fentanyl-related substance as defined in schedule
3 I(e) of section 202(c);”;

4 (2) in subparagraph (B), by striking clause (vi)
5 and inserting the following:

6 “(vi)(I) 40 grams or more of a mixture or sub-
7 stance containing a detectable amount of fentanyl;
8 or

9 “(II) 10 grams or more of a mixture or sub-
10 stance containing a detectable amount of any ana-
11 logue of fentanyl that is controlled in schedule I or
12 II or that is treated as a schedule I controlled sub-
13 stance pursuant to section 203(a), except for a
14 fentanyl-related substance as defined in schedule
15 I(e) of section 202(c);” and

16 (3) in subparagraph (C), by inserting “, includ-
17 ing a fentanyl-related substance as defined in sched-
18 ule I(e) of section 202(c),” after “a controlled sub-
19 stance in schedule I or II.”.

20 **SEC. 4. PENALTY PROVISIONS WITH RESPECT TO**
21 **FENTANYL-RELATED SUBSTANCES—IMPORT**
22 **AND EXPORT OFFENSES.**

23 Section 1010(b) of the Controlled Substances Import
24 and Export Act (21 U.S.C. 960(b)) is amended—

1 (1) in paragraph (1), by striking subparagraph
2 (F) and inserting the following:

3 “(F)(i) 400 grams or more of a mixture or sub-
4 stance containing a detectable amount of fentanyl;
5 or

6 “(ii) 100 grams or more of a mixture or sub-
7 stance containing a detectable amount of any ana-
8 logue of fentanyl that is controlled in schedule I or
9 II or that is treated as a schedule I controlled sub-
10 stance pursuant to section 203(a) of the Controlled
11 Substances Act, except for a fentanyl-related sub-
12 stance as defined in schedule I(e) of section 202(c)
13 of the Controlled Substances Act;”;

14 (2) in paragraph (2), by striking subparagraph
15 (F) and inserting the following:

16 “(F)(i) 40 grams or more of a mixture or sub-
17 stance containing a detectable amount of fentanyl;
18 or

19 “(ii) 10 grams or more of a mixture or sub-
20 stance containing a detectable amount of any ana-
21 logue of fentanyl that is controlled in schedule I or
22 II or that is treated as a schedule I controlled sub-
23 stance pursuant to section 203(a) of the Controlled
24 Substances Act, except for a fentanyl-related sub-

1 stance as defined in schedule I(e) of section 202(c)
2 of the Controlled Substances Act;” and

3 (3) in paragraph (3), by inserting “including a
4 fentanyl-related substance as defined in schedule
5 I(e) of section 202(c) of the Controlled Substances
6 Act,” after “a controlled substance in schedule I or
7 II.”.

8 **SEC. 5. REMOVAL FROM SCHEDULE I OF FENTANYL-RE-**
9 **LATED SUBSTANCES.**

10 Section 201 of the Controlled Substances Act (21
11 U.S.C. 811) is amended by adding at the end the following
12 new subsection:

13 “(k) REMOVAL FROM SCHEDULE I OF FENTANYL-
14 RELATED SUBSTANCES.—

15 “(1) DETERMINATION RESULTING IN RE-
16 MOVAL.—If the Secretary determines, taking into
17 consideration factors as set forth in paragraph (3),
18 that a fentanyl-related substance has a potential for
19 abuse that is less than the drugs or other substances
20 in schedule V—

21 “(A) the Secretary shall submit to the At-
22 torney General a scientific and medical evalua-
23 tion of that fentanyl-related substance sup-
24 porting that determination;

1 “(B) the Secretary shall submit any such
2 evaluation and determination in writing and in-
3 clude the bases therefor;

4 “(C) the scientific and medical determina-
5 tion of the Secretary contained in such evalua-
6 tion shall be binding on the Attorney General;
7 and

8 “(D) not later than 90 days after receiving
9 such evaluation and determination, the Attor-
10 ney General shall issue an order removing such
11 fentanyl-related substance from the schedules
12 under section 202.

13 “(2) DETERMINATION RESULTING IN RESCHED-
14 ULING.—If the Secretary determines, taking into
15 consideration factors as set forth in paragraph (3),
16 that a fentanyl-related substance has a potential for
17 abuse that is less than the drugs or other substances
18 in schedules I and II—

19 “(A) the Secretary shall submit to the At-
20 torney General a scientific and medical evalua-
21 tion of that fentanyl-related substance sup-
22 porting that determination;

23 “(B) the Secretary shall submit any such
24 evaluation and determination in writing and in-
25 clude the bases therefor;

1 “(C) the scientific and medical determina-
2 tion of the Secretary contained in such evalua-
3 tion shall be binding on the Attorney General;
4 and

5 “(D) not later than 90 days after receiving
6 such evaluation, the Attorney General shall
7 issue an order removing such fentanyl-related
8 substance from schedule I and controlling such
9 substance under schedule III.

10 “(3) EVALUATION FACTORS.—

11 “(A) IN GENERAL.—In making a deter-
12 mination under paragraph (1) or (2), the Sec-
13 retary—

14 “(i) shall consider—

15 “(I) the factor listed in para-
16 graph (2) of subsection (c);

17 “(II) the factors listed in para-
18 graphs (1), (3), and (6) of such sub-
19 section to the extent evidence exists
20 with respect to such factors; and

21 “(III) any information submitted
22 to the Secretary by the Attorney Gen-
23 eral for purposes of such determina-
24 tion; and

1 “(ii) may consider the factors listed in
2 paragraphs (4), (5), and (7) of subsection
3 (c) if the Secretary finds that evidence ex-
4 ists with respect to such factors.

5 “(B) CONSIDERATION OF SCIENTIFIC EVI-
6 DENCE OF PHARMACOLOGICAL EFFECT.—

7 “(i) IN GENERAL.—For the purposes
8 of subparagraph (A)(i)(I), consideration by
9 the Secretary of the results of an assess-
10 ment consisting of the studies described in
11 clause (ii) shall suffice to constitute consid-
12 eration of the factor listed in paragraph
13 (2) of subsection (c) if—

14 “(I) each such study is per-
15 formed according to scientific methods
16 and protocols commonly accepted in
17 the scientific community; and

18 “(II) the Secretary determines
19 that such assessment is adequate for
20 such purposes.

21 “(ii) DESCRIBED STUDIES.—The
22 studies described in this clause are any of
23 the following:

24 “(I) A receptor binding study
25 that can demonstrate whether the

1 substance has affinity for the human
2 mu opioid receptor.

3 “(II) An in vitro functional assay
4 that can demonstrate whether the
5 substance has agonist activity at the
6 human mu opioid receptor.

7 “(III) One or more in vivo ani-
8 mal behavioral studies that can dem-
9 onstrate whether the substance has
10 abuse-related drug effects consistent
11 with mu opioid agonist activity, such
12 as demonstrating similarity to the ef-
13 fects of morphine.

14 “(4) ADVANCE NOTICE REGARDING EVALUA-
15 TION AND CONCLUSION.—The Secretary shall give
16 the Attorney General at least 30 days notice before
17 sending the Attorney General an evaluation and de-
18 termination under paragraph (1) or (2) with respect
19 to a fentanyl-related substance.

20 “(5) EXCEPTION FOR TREATY OBLIGATIONS.—
21 If a fentanyl-related substance is a substance that
22 the United States is obligated to control under inter-
23 national treaties, conventions, or protocols in effect
24 on the date of enactment of the Save Americans

1 from the Fentanyl Emergency Act, this subsection
2 shall not require the Attorney General—

3 “(A) to remove such substance from con-
4 trol; or

5 “(B) to place such substance in a schedule
6 less restrictive than that which the Attorney
7 General determines is necessary to carry out
8 such obligations.

9 “(6) IDENTIFICATION OF FENTANYL-RELATED
10 SUBSTANCES.—If the Attorney General or any offi-
11 cial of the Department of Justice determines that a
12 substance is a fentanyl-related substance, the Attor-
13 ney General shall—

14 “(A) within 30 days of such determination,
15 notify the Secretary; and

16 “(B) include in such notification the iden-
17 tity of the substance, its structure, and the
18 basis for the determination.

19 “(7) PETITIONS FOR REMOVING A FENTANYL-
20 RELATED SUBSTANCE.—

21 “(A) IN GENERAL.—If a person petitions
22 the Attorney General to remove a fentanyl-re-
23 lated substance from schedule I(e) or to re-
24 schedule such a substance to another schedule,
25 the Attorney General shall consider such a peti-

1 tion in accordance with the procedures and
2 standards set forth in—

3 “(i) subsections (a) and (b) of this
4 section; and

5 “(ii) section 1308.43 of title 21, Code
6 of Federal Regulations (or any successor
7 regulations).

8 “(B) ATTORNEY GENERAL TO INFORM
9 SECRETARY.—Within 30 days of receiving such
10 a petition, the Attorney General shall forward a
11 copy of the petition to the Secretary.

12 “(C) DETERMINATION PROCEDURE NOT
13 PRECLUDED BY FILING OF PETITION.—The fil-
14 ing of a petition under this paragraph shall not
15 preclude the Secretary from making a deter-
16 mination and sending an evaluation under para-
17 graph (1) or (2).

18 “(8) RULE OF CONSTRUCTION.—Nothing in
19 this subsection shall be construed to preclude the At-
20 torney General from transferring a substance listed
21 in schedule I to another schedule, or removing such
22 substance entirely from the schedules, pursuant to
23 other provisions of this section and section 202.

24 “(9) SUBSEQUENT CONTROLLING OF REMOVED
25 SUBSTANCE.—A substance removed from schedule I

1 pursuant to this subsection may, at any time, be
2 controlled pursuant to the other provisions of this
3 section and section 202 without regard to the re-
4 moval pursuant to this subsection.

5 “(10) EVALUATIONS OR STUDIES.—The Sec-
6 retary may enter into contracts or other agreements
7 to conduct or support evaluations or studies of
8 fentanyl-related substances.

9 “(11) DEFINITION.—In this subsection, the
10 term ‘fentanyl-related substance’ means a fentanyl-
11 related substance as defined in schedule I(e) of sec-
12 tion 202(c).”.

13 **SEC. 6. PAST CASES INVOLVING REMOVED OR RESCHED-**
14 **ULED SUBSTANCES.**

15 (a) DOMESTIC CASES.—Section 401(b) of the Con-
16 trolled Substances Act (21 U.S.C. 841(b)) is amended by
17 adding at the end the following:

18 “(8) PAST CONVICTIONS INVOLVING FENTANYL-RE-
19 LATED SUBSTANCE.—

20 “(A) IN GENERAL.—In the case of a defendant
21 whose offense of conviction under this title involved
22 a fentanyl-related substance (as defined in schedule
23 I(e) of section 202(c) as of the date the offense was
24 committed) that has since been removed from des-
25 ignation as a fentanyl-related substance for purposes

1 of this title and has been placed on any schedule
2 other than schedule I or II or has been removed
3 from the controlled substance schedules, the sen-
4 tencing court may, on motion of the defendant, the
5 Bureau of Prisons, the attorney for the Government,
6 or on its own motion, after considering the factors
7 set forth in section 3553(a) of title 18, United
8 States Code, vacate the previously imposed sentence,
9 or impose a reduced sentence on any count of con-
10 viction as if the removal or placement was in effect
11 at the time that the offense was committed. Nothing
12 in this section may be construed to require a court
13 to vacate or reduce any sentence.

14 “(B) DEFENDANT NOT REQUIRED TO BE
15 PRESENT.—Notwithstanding rule 43 of the Federal
16 Rules of Criminal Procedure, the defendant is not
17 required to be present at any hearing on whether to
18 vacate or reduce a sentence pursuant to this sec-
19 tion.”.

20 (b) IMPORT AND EXPORT CASES.—Section 1010(b)
21 of the Controlled Substances Import and Export Act (21
22 U.S.C. 960(b)) is amended by adding at the end the fol-
23 lowing:

24 “(8) In the case of a defendant whose offense of con-
25 viction under this title involved a fentanyl-related sub-

1 stance (as defined in schedule I(e) of section 202(c) of
2 the Controlled Substances Act as of the date the offense
3 was committed) that has since been removed from des-
4 ignation as a fentanyl-related substance for purposes of
5 this title and has been placed on any schedule other than
6 schedule I or II or has been removed from the controlled
7 substance schedules, the sentencing court may, on motion
8 of the defendant, the Bureau of Prisons, the attorney for
9 the Government, or on its own motion, after considering
10 the factors set forth in section 3553(a) of title 18, United
11 States Code, vacate the previously imposed sentence, or
12 impose a reduced sentence on any count of conviction as
13 if the removal or placement was in effect at the time that
14 the offense was committed. Nothing in this section may
15 be construed to require a court to vacate or reduce any
16 sentence.”.

17 **SEC. 7. REGISTRATION REQUIREMENTS RELATED TO RE-**
18 **SEARCH.**

19 (a) **ALTERNATIVE REGISTRATION PROCESS FOR**
20 **SCHEDULE I RESEARCH.**—Section 303 of the Controlled
21 Substances Act (21 U.S.C. 823) is amended by adding at
22 the end the following new subsection:

23 “(m) **SPECIAL PROVISIONS FOR THOSE CONDUCTING**
24 **CERTAIN RESEARCH WITH SCHEDULE I CONTROLLED**
25 **SUBSTANCES.**—

1 “(1) IN GENERAL.—Notwithstanding subsection
2 (f), a practitioner may conduct research that is de-
3 scribed in paragraph (2) and that is with one or
4 more controlled substances in schedule I if one of
5 the following conditions is satisfied:

6 “(A) RESEARCHER WITH A CURRENT
7 SCHEDULE I OR II RESEARCH REGISTRATION.—
8 If the practitioner is registered to conduct re-
9 search with a controlled substance in schedule
10 I or II, the practitioner may conduct research
11 under this paragraph 30 days after the practi-
12 tioner has sent a notice to the Attorney General
13 containing the following information, with re-
14 spect to each substance with which the research
15 will be conducted:

16 “(i) The chemical name of the sub-
17 stance.

18 “(ii) The quantity of the substance to
19 be used in such research.

20 “(iii) Demonstration that the research
21 is described in paragraph (2), which dem-
22 onstration can be satisfied—

23 “(I) in the case of research de-
24 scribed in paragraph (2)(A), by sup-
25 plying the number of the application

1 submitted under section 505(i) of the
2 Federal Food, Drug, and Cosmetic
3 Act or section 351(a)(3) of the Public
4 Health Service Act and the sponsor of
5 record on such application; or

6 “(II) in the case of research de-
7 scribed in paragraph (2)(B), by iden-
8 tifying the sponsoring agency and
9 supplying the number of the grant,
10 contract, cooperative agreement, other
11 transaction, or project.

12 “(iv) Demonstration that the re-
13 searcher is authorized to conduct research
14 with respect to the substance under the
15 laws of the State in which the research will
16 take place.

17 “(B) RESEARCHER WITHOUT A CURRENT
18 SCHEDULE I OR II RESEARCH REGISTRATION.—
19 If the practitioner is not currently registered to
20 conduct research with a controlled substance in
21 schedule I or II—

22 “(i) the practitioner may send a no-
23 tice to the Attorney General containing the
24 information listed in subparagraph (A),

1 with respect to each substance with which
2 the research will be conducted;

3 “(ii) the Attorney General shall treat
4 such notice as a sufficient application for
5 a research registration; and

6 “(iii) within 45 days after receiving
7 such a notice that contains all information
8 required by subparagraph (A), the Attor-
9 ney General shall register the applicant, or
10 serve an order to show cause upon the ap-
11 plicant in accordance with section 304(c).

12 “(C) VERIFICATION OF INFORMATION.—
13 On request from the Attorney General, the Sec-
14 retary of Health and Human Services or the
15 Secretary of Veterans Affairs, as appropriate,
16 shall verify information submitted by an appli-
17 cant under subparagraph (A)(iii).

18 “(2) RESEARCH SUBJECT TO EXPEDITED PRO-
19 CEDURE.—Research described in this paragraph is
20 research that—

21 “(A) is the subject of an application under
22 section 505(i) of the Federal Food, Drug, and
23 Cosmetic Act or section 351(a)(3) of the Public
24 Health Service Act for the investigation of a
25 drug which is in effect in accordance with sec-

1 tion 312.40 of title 21, Code of Federal Regula-
2 tions; or

3 “(B) is conducted by the Department of
4 Health and Human Services, the Department of
5 Justice, or the Department of Veterans Affairs
6 or is funded partly or entirely by a grant, con-
7 tract, cooperative agreement, or other trans-
8 action from the Department of Health and
9 Human Services, the Department of Justice, or
10 the Department of Veterans Affairs.

11 “(3) ELECTRONIC SUBMISSIONS.—The Attorney
12 General shall provide a means to allow practitioners
13 to submit notifications under paragraph (1) elec-
14 tronically.

15 “(4) LIMITATION ON AMOUNTS.—A practitioner
16 conducting research with a controlled substance in
17 schedule I pursuant to this subsection shall be al-
18 lowed to possess only the amounts of the controlled
19 substance in schedule I identified in—

20 “(A) the notification to the Attorney Gen-
21 eral under paragraph (1); or

22 “(B) if the practitioner needs additional
23 amounts for the research, a supplemental notifi-
24 cation under this subsection that includes the
25 practitioner’s name, the additional quantity

1 needed of the substance, and an attestation
2 that the research to be conducted with the sub-
3 stance is consistent with the scope of the re-
4 search that was the subject of the notification
5 under paragraph (1).

6 “(5) IMPORTATION AND EXPORTATION RE-
7 QUIREMENTS NOT AFFECTED.—Nothing in this sec-
8 tion alters the requirements of part A of title III re-
9 garding the importation and exportation of con-
10 trolled substances.”.

11 (b) SEPARATE REGISTRATIONS NOT REQUIRED FOR
12 ADDITIONAL RESEARCHER IN SAME INSTITUTION.—Sub-
13 section (c) of section 302 of the Controlled Substances Act
14 (21 U.S.C. 822) is amended by adding at the end the fol-
15 lowing:

16 “(4) An agent or employee of a research insti-
17 tution that is conducting research with a controlled
18 substance if—

19 “(A) such agent or employee is acting
20 within the scope of his or her professional prac-
21 tice;

22 “(B) another agent or employee of such in-
23 stitution is registered to conduct research with
24 a controlled substance in the same schedule;

25 “(C) the researcher who is so registered—

1 “(i) informs the Attorney General of
2 the name, position title, and employing in-
3 stitution of the agent or employee who is
4 not separately registered;

5 “(ii) authorizes such agent or em-
6 ployee to perform research under the reg-
7 istered researcher’s registration; and

8 “(iii) affirms that all acts taken by
9 such agent or employee involving controlled
10 substances shall be attributable to the reg-
11 istered researcher, as if the researcher had
12 directly committed such acts, for purposes
13 of any proceeding under section 304(a) to
14 suspend or revoke the registration of the
15 registered researcher; and

16 “(D) the Attorney General does not, within
17 30 days of receiving the information, authoriza-
18 tion, and affirmation described in subparagraph
19 (C), refuse, for a reason listed in section
20 304(a), to allow such agent or employee to pos-
21 sess such substance without a separate registra-
22 tion.”.

23 (c) SINGLE REGISTRATION FOR RELATED RESEARCH
24 SITES.—Such section 302(e) of the Controlled Substances

1 Act (21 U.S.C. 822(e)) is amended by adding at the end
2 the following:

3 “(4)(A) Notwithstanding paragraph (1), a person
4 registered to conduct research with a controlled substance
5 under section 303(f) may conduct such research at mul-
6 tiple sites under a single registration if—

7 “(i) such research occurs exclusively at sites
8 which are all within the same city or county and are
9 all under the control of the same institution, organi-
10 zation, or agency; and

11 “(ii) the researcher notifies the Attorney Gen-
12 eral, prior to commencing such research, of all sites
13 where—

14 “(I) the research will be conducted; or

15 “(II) the controlled substance will be
16 stored or administered.

17 “(B) A site described by subparagraph (A) shall be
18 included in such registration only if the researcher has no-
19 tified the Attorney General of such site—

20 “(i) in the application for such registration; or

21 “(ii) before the research is conducted, or before
22 the controlled substance is stored or administered, at
23 such site.

1 “(C) The Attorney General may, in consultation with
2 the Secretary of Health and Human Services, issue regu-
3 lations addressing—

4 “(i) the manner in which controlled substances
5 may be delivered to research sites described in sub-
6 paragraph (A);

7 “(ii) the storage and security of controlled sub-
8 stances at such research sites;

9 “(iii) the maintenance of records for such re-
10 search sites; and

11 “(iv) any other matters necessary to ensure ef-
12 fective controls against diversion at such research
13 sites.”.

14 (d) NEW INSPECTION NOT REQUIRED IN CERTAIN
15 SITUATIONS.—Subsection (f) of section 302 of the Con-
16 trolled Substances Act (21 U.S.C. 822) is amended—

17 (1) by striking “(f) The” and inserting “(f)(1)
18 The”; and

19 (2) by adding at the end the following:

20 “(2)(A) A new inspection by the Attorney General of
21 a registered location is not required if a person is reg-
22 istered under this title to conduct research with a con-
23 trolled substance and applies for a registration, or for a
24 modification of a registration, to conduct research with a
25 second controlled substance that is—

1 “(i) in the same schedule as the first controlled
2 substance; or

3 “(ii) is in a schedule with a higher numerical
4 designation than the schedule of the first controlled
5 substance.

6 “(B) Nothing in this paragraph shall prohibit the At-
7 torney General from conducting any inspection if the At-
8 torney General deems it necessary to ensure that the reg-
9 istrant maintains effective controls against diversion.”.

10 (e) CONTINUATION OF RESEARCH ON SUBSTANCES
11 NEWLY ADDED TO SCHEDULE I.—Section 302 of the
12 Controlled Substances Act (21 U.S.C. 822) is amended
13 by adding at the end the following:

14 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
15 NEWLY ADDED TO SCHEDULE I.—If a person is con-
16 ducting research on a substance at the time the substance
17 is added to schedule I, and such person is already reg-
18 istered under this title to conduct research with a con-
19 trolled substance in schedule I, then—

20 “(1) the person shall, within 90 days of the
21 scheduling in schedule I, submit a completed appli-
22 cation for registration under this title or modifica-
23 tion of an existing registration under this title, to
24 conduct research on such substance, in accordance
25 with regulations issued by the Attorney General;

1 “(2) the person may, notwithstanding sub-
2 sections (a) and (b), continue to conduct the re-
3 search on such substance until—

4 “(A) the person withdraws such applica-
5 tion; or

6 “(B) the Attorney General serves on the
7 person an order to show cause proposing the
8 denial of the application pursuant to section
9 304(c);

10 “(3) if the Attorney General serves such an
11 order to show cause and the person requests a hear-
12 ing, such hearing shall be held on an expedited basis
13 and not later than 45 days after the request is
14 made, except that the hearing may be held at a later
15 time if so requested by the person; and

16 “(4) if the person sends a copy of the applica-
17 tion required by paragraph (1) to a manufacturer or
18 distributor of such substance, receipt of such copy
19 by such manufacturer or distributor shall constitute
20 sufficient evidence that the person is authorized to
21 receive such substance.”.

22 (f) TREATMENT OF CERTAIN MANUFACTURING AC-
23 TIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of
24 the Controlled Substances Act (21 U.S.C. 822), as amend-

1 ed by subsection (e), is further amended by adding at the
2 end the following:

3 “(i) TREATMENT OF CERTAIN MANUFACTURING AC-
4 TIVITIES AS COINCIDENT TO RESEARCH.—

5 “(1) IN GENERAL.—Except as specified in
6 paragraph (3), a person who is registered to perform
7 research on a controlled substance may perform
8 manufacturing activities with small quantities of
9 that substance, including activities listed in para-
10 graph (2), without being required to obtain a manu-
11 facturing registration, if such activities are per-
12 formed for the purpose of the research and if the ac-
13 tivities and the quantities of the substance involved
14 in those activities are stated in—

15 “(A) a notification submitted to the Attor-
16 ney General under section 303(m);

17 “(B) a protocol filed with an application
18 for registration approval under section 303(f);
19 or

20 “(C) a notification to the Attorney General
21 that includes the registrant’s name and an at-
22 testation that the research to be conducted with
23 the small quantities of manufactured substance
24 is consistent with the scope of the research that
25 is the basis for the registration.

1 “(2) ACTIVITIES INCLUDED.—Activities per-
2 mitted under paragraph (1) include—

3 “(A) processing the substance to create ex-
4 tracts, tinctures, oils, solutions, derivatives, or
5 other forms of the substance consistent with the
6 information provided as part of a notification
7 submitted to the Attorney General under sec-
8 tion 303(m) or a research protocol filed with
9 the application for registration approval; and

10 “(B) dosage form development studies per-
11 formed for the purpose of satisfying regulatory
12 requirements of the Food and Drug Adminis-
13 tration for submitting an investigational new
14 drug application.

15 “(3) EXCEPTION REGARDING MARIHUANA.—
16 The authority under paragraph (1) to manufacture
17 substances does not include authority to grow mari-
18 huana.”.

19 (g) TRANSPARENCY REGARDING SPECIAL PROCE-
20 DURES.—Section 303 of such Act (21 U.S.C. 823), as
21 amended by subsection (a), is further amended by adding
22 at the end the following:

23 “(n) TRANSPARENCY REGARDING SPECIAL PROCE-
24 DURES.—

1 “(1) IN GENERAL.—If the Attorney General de-
2 termines, with respect to a controlled substance, that
3 an application by a practitioner to conduct research
4 with such substance should be considered under a
5 process, or subject to criteria, different from the
6 process or criteria applicable to applications to con-
7 duct research with other controlled substances in the
8 same schedule, the Attorney General shall make
9 public, including by posting on the website of the
10 Drug Enforcement Administration—

11 “(A) the identities of all substances for
12 which such determinations have been made;

13 “(B) the process and criteria that will be
14 applied to applications to conduct research with
15 such substances; and

16 “(C) how such process and criteria differ
17 from those applicable to applications to conduct
18 research with other controlled substances in the
19 same schedule.

20 “(2) TIMING OF POSTING.—The Attorney Gen-
21 eral shall make such information public upon mak-
22 ing such determination, regardless of whether a
23 practitioner has submitted such an application at
24 that time.”.

1 **SEC. 8. RULEMAKING.**

2 (a) INTERIM FINAL RULES.—The Attorney Gen-
3 eral—

4 (1) not later than 1 year of the date of enact-
5 ment of this Act, shall issue rules to implement this
6 Act and the amendments made by this Act; and

7 (2) may issue such rules as interim final rules.

8 (b) PROCEDURE FOR FINAL RULE.—A rule issued by
9 the Attorney General as an interim final rule under sub-
10 section (a) shall become immediately effective as an in-
11 terim final rule without requiring the Attorney General to
12 demonstrate good cause therefor. The interim final rule
13 shall give interested persons the opportunity to comment
14 and to request a hearing. After the conclusion of such pro-
15 ceedings, the Attorney General shall issue a final rule in
16 accordance with section 553 of title 5, United States Code.

17 **SEC. 9. GAO REPORT.**

18 (a) IN GENERAL.—Not more than 4 years after the
19 date of enactment of this Act, the Comptroller General
20 of the United States shall submit to the Committees on
21 Energy and Commerce and the Judiciary of the House
22 of Representatives and the Committee on the Judiciary
23 of the Senate a report analyzing the implementation and
24 impact, to the extent information is available, of perma-
25 nent class scheduling pursuant to schedule I(e) of section
26 202(e) of the Controlled Substances Act, as added by sec-

1 tion 2 of this Act, of fentanyl-related substances (as de-
2 fined in such schedule I(e)), which report shall include—

3 (1) an analysis of the impact on research of
4 fentanyl-related substances;

5 (2) an analysis of any actions taken to remove
6 or reschedule in a different class any fentanyl-re-
7 lated substance;

8 (3) an analysis of the impact of permanent
9 scheduling on the unlawful importation, manufac-
10 ture, trafficking, and use of fentanyl-related sub-
11 stances, taking into consideration data collected con-
12 cerning the proliferation of fentanyl-related sub-
13 stances since class scheduling was instituted;

14 (4) an analysis of sentences attributable to
15 criminal charges involving fentanyl-related sub-
16 stances, comparing those sentences to sentences at-
17 tributable to criminal charges involving fentanyl and
18 individually scheduled fentanyl analogues; and

19 (5) an analysis of the efficacy of class sched-
20 uling generally, in terms of reducing the prolifera-
21 tion of new controlled substance analogues.

22 (b) CONSULTATIONS.—In developing the report re-
23 quired by subsection (a), the Comptroller General—

24 (1) shall consider the views of the Secretary of
25 Health and Human Services, the Attorney General,

1 the Secretary of Homeland Security, the Secretary
2 of State, the Director of the Office of National Drug
3 Control Policy, the scientific and medical research
4 community, the State and local law enforcement
5 community, and the civil rights and criminal justice
6 reform communities; and

7 (2) to the greatest extent possible, should base
8 such report on reliable data and empirical informa-
9 tion.

